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## **REMARKS**

### **I. Status of the Claims**

Claims 55-96 are currently in the case.

### **II. Double patenting rejection**

The Examiner has rejected claims 55-96 under the judicially created doctrine of obviousness-type double patenting over claims 1-17 of the commonly owned U.S. Patent No. 6,270,791. Attached is a terminal disclaimer in compliance with 37 C.F.R. 1.321(c) that is sufficient to overcome this rejection.

### **III. Claim rejections under 35 U.S.C. §102**

#### **A. The '173 patent neither teaches nor suggests water soluble peptides that precipitate in alcohol.**

The Examiner has rejected claims 55, 57, 59-61, 69, 77, 79, 81-85, 87-89, 93, 94 and 95 under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 4,495,173 ('173). In particular, the Examiner has asserted that the steps of oxidizing animal or human hair, feathers, claws, horns, hoofs, scales and the like is disclosed, that the oxidation is followed by neutralization then gel filtration, and that the solvent used to solubilize keratin is ethanol or methanol. Applicants respectfully traverse the rejection.

Applicants submit that the '173 patent describes various types of keratin derivative compositions and that the Action appears to recite individual steps from the various methods that are, however, never combined into a single method to describe the claimed products. Therefore,

none of the methods or products described in the '173 patent include all the steps of claim 55, and thus do not anticipate the claimed invention.

Applicants direct Examiner's attention especially to the recitation in claim 55 of the following step:

adding a water-miscible organic solvent to said water soluble portion, such that a precipitate is formed;

The inclusion of this step indicates that the peptides are soluble in water, but precipitate in a water miscible organic solvent such as methanol, ethanol, acetone, tetrahydrofuran or a combination thereof (see claim 59). The characteristic cited in col. 5, lines 53-54, that the product of the enzyme hydrolysis method is soluble in ethanol, methanol, etc. actually teaches away from the claimed invention which is insoluble (precipitates) in such solvents.

Examiner's attention is also drawn to the recitation in claim 55 that the claimed material is first oxidized. Therefore, only the oxidized keratin derivatives described in the '173 patent could possibly be relevant to the present claims. The passage cited by the Examiner at col. 5 lns. 1-3 and 53-55, do not describe steps in conjunction with the oxidation protocol, nor is there any suggestion that the steps be combined with it. For example, the passage at col. 5, lns. 1-3 relates to a method of hydrolysis of keratin material with alkali, and the passage at col. 5, lns. 53-54 discusses products of enzyme hydrolysis of keratin materials.

In addition, Applicants find no description in any of the oxidation methods of a product that is water soluble and precipitates in alcohol. Rather, the '173 patent states that the oxidation products are "insoluble in polar solvents, so that it is necessary to add such products in the form of alkali salts." Thus in addition to teaching away from the precipitation of the oxidized keratin material with water-miscible organic solvents, the oxidation products of the '173 patent are not the water **soluble** products of the oxidation step, but are instead water **insoluble** products.

The '173 patent therefore can in no way be said to teach or suggest the claimed invention, and Applicants respectfully request that all rejections over this patent be withdrawn.

**B. Neither does the '138 patent teach or suggest water soluble peptides that are precipitated in a water miscible solvent.**

The Examiner has rejected claims 55-57, 59-61 and 94 under 35 U.S.C. 102(b) as being anticipated under 35 U.S.C. §102(b) by U.S. Pat. No. 5,276,138 ('138), stating that "[t]he method of production included the steps of oxidation by hydrogen peroxide or peracetic acid; precipitation of a powder; and using solvent such as acetone, methanol or ethanol".

Applicants respectfully traverse the rejection and submit that the '138 patent describes a different product than that which is the subject of the present claims. As in the discussion of the '173 patent, Applicants find no description of an oxidized keratin product that is precipitated from aqueous solution by a water miscible solvent such as methanol, etc. The '138 patent describes a product obtained by an acid precipitation step. For example, at column 5, lines 67 and 68 is a description of precipitating a gel by decreasing the pH to 3 with acetic acid. In Example 2 this product is again precipitated in citric acid (col. 6, line 23) and the remaining examples are drawn to the use of other acids to precipitate the product.

In contrast, the present claims require "adding a water-miscible organic solvent to said water soluble portion, such that a precipitate is formed". The '138 patent does not disclose the production of precipitate by the addition of a water-miscible organic solvent; the precipitate is obtained instead by acid treatment.

The '138 patent therefore does not disclose or suggest a step in which a water-miscible organic solvent is added to the water soluble protein such that a precipitate is formed. Therefore the present claims are in no way anticipated nor suggested by the teachings of the '138 patent. Applicants respectfully request, therefore, that this rejection be withdrawn.

**C. The '583 patent appears to only describe products produced by first reducing the disulfide bonds of keratin and thus neither teaches nor suggests the water soluble peptides of the present claims.**

The Examiner has rejected claims 55, 57, 59-61, 65, 69-71, 73-84 and 93 under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 5,763,583 ('583). The Examiner states that the '583 patent discloses water soluble protein derived from human or animal hair that is produced by a process comprising the steps of oxidizing using hydrogen peroxide, and neutralization of the produced aqueous solution followed by filtration. The '583 patent is also said to disclose the use of organic solvents such as methanol and ethanol and to produce soluble protein in the form of a film.

Applicants submit that the Official Action oversimplifies the process of the '583 patent, and thereby underestimates the fundamental differences with the present claimed invention. The chemical process and the products described in the '583 patent are very different than that in the present claims. For example, the product that results from first, reduction with thioglycolic acid, followed by oxidation, contains carboxymethyl disulfides as discussed at col 2, lines 54 and 55, and further at col 3, lines 19 and 20. The presence of this group is enough to distinguish the claimed peptides from the description in the '583 patent. In addition, Applicants find no description of peptides precipitated from aqueous solution by a water miscible solvent.

The Action points to a description of the use of a mixed solvent of an organic solvent with water, however, this appears to be describing the solvent for a plasticizer, rather than for precipitation of peptides. Thus the process of the present claims are not anticipated by the methods of the '583 patent and neither does the '583 patent describe or suggest the compositions of the present claims. Applicants respectfully request, therefore, that all rejections over the '583 patent be withdrawn.

**D. The '552 patent does not describe the water soluble peptides of the present claims.**

The Examiner has rejected claims 55-57, 65, 69-71, 84 and 93 under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 5,932,552 ('552). The '552 patent describes formation of a keratin hydrogel where the keratin has been partially oxidized. "The partially oxidized hair can be recovered with filtration, rinsed with deionized water, dried under vacuum, and ground to powder." (Col. 2, Ins. 61-64). After such filtration, the keratin material is treated with a reducing agent and a soluble keratin fraction is obtained. The Examiner points to col. 2, line 67 to col. 3, line 3 of the '552 patent as showing a step in which there is neutralization by a base, however it should be noted that the neutralization step involves the treatment of partially oxidized material that has been rinsed in deionized water. Therefore the step involves neutralization of the water **insoluble** fraction obtained after partial oxidation, not the water **soluble** portion required by the claims.

For example, the process of claim 55 includes the step:

"filtering said aqueous oxidizing solution to obtain a water soluble portion."

The water soluble portion is then neutralized and precipitated. In the process described in the '552 patent, the insoluble portion that was retained by the filter is used to produce the hydrogel material. Thus, the '552 patent fails to ever mention the use of water-miscible organic solvents such as ethanol, methanol or acetone, because the portion containing the peptides that can be precipitated as in the present claims is discarded in the process described in the '552 patent.

The '552 patent thus can in no way be said to teach or suggest the claimed invention, and in fact, teaches away from the present claims. Applicants respectfully request, therefore, that all rejections over the '552 patent be withdrawn.

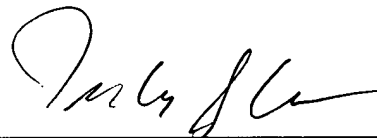
**IV. Claim rejections under 35 U.S.C. §103(a)**

The Examiner has rejected claims 55-96 under 35 U.S.C. §103(a) as being unpatentable over any of U.S. patents '173, '138, '583 or '552 each by itself or in combination with any of U.S. Pat. No. 5,948,432 ('432), U.S. Pat. No. 5,900,245 ('245), U.S. Pat. No. 5,358,935 ('935), or FR 2540381 ('381).

As discussed above, U.S. patents '173, '138, '583 and '552 do not teach or suggest the claimed invention. Neither do the secondary references teach or suggest the claimed invention. The '432 patent appears to describe only the use of cross-linked insoluble keratin products and the '935 patent describes colloidal suspensions of keratin. The '245 patent does not appear to discuss keratin or keratin derivatives at all, nor does it appear to include any process for producing a peptide composition. Neither does the FR '393 patent describe or suggest the water soluble peptides of the invention.

Therefore the combination of the '173, '138, '583 and '552 patents with any or all of the '432, '245, '935 or '381 patents would fail to supply the elements required to render the present claims obvious. Applicants respectfully request, therefore, that the Examiner withdraw the rejection of the present claims under 35 U.S.C. §103.

Respectfully submitted,



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